

# **EXHIBIT B**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN, AND  
IRBESARTAN PRODUCTS LIABILITY  
LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Thomas I. Vanaskie (Ret.),  
Magistrate Judge

**DECLARATION OF DR. MIN LI**

1. I am Vice President of Analytic Operations for Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), with responsibility for overseeing company-wide analytical research and development, and providing technical leadership in API quality control operations. I submit this declaration in support of the motion to seal certain confidential documents filed by Defendants ZHP, Prinston Pharmaceutical Inc. (“Prinston”) and Huahai U.S. Inc. (“Huahai U.S.”).

2. I state that I have reviewed each of the below documents Plaintiffs intended to file as Exhibits 8, 14, 15, and 16 to ECF No. 1405, and that this declaration is made on the basis of my personal knowledge.

3. **ZHP02731217** (ECF No. 1405, Ex. 8) (designated “RESTRICTED CONFIDENTIAL INFORMATION”): This document contains non-public, internal communications between ZHP employees dated January 13, 2018 regarding testing of the ZHP Parties’ irbesartan intermediate compounds. These testing practices and procedures are proprietary, related to intermediate compounds rather than the finished API product, and unrelated to the claims at issue in this litigation. Disclosure of the ZHP Parties’ testing practices and procedures to the ZHP Parties’ direct competitors would result in significant competitive

harm by allowing them to benefit from the ZHP Parties' research and development while the FDA restricts the ZHP Parties from exporting its products into the U.S. market. Such disclosure would impede the ability of the ZHP Parties to compete in the highly competitive generic pharmaceutical manufacturing market.

4. **ZHP02710347** (ECF No. 1405, Ex. 14) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): This document is an investigation report prepared by the ZHP Parties, which details proprietary specifications and testing methods for impurities related to irbesartan. This information is highly confidential, proprietary, and competitively sensitive because it reveals how the ZHP Parties sought optimize their procedures for manufacturing irbesartan API by addressing certain technical changes observed during process improvements, and the specific tests conducted to investigate the changes, which were the result of significant research and development by ZHP. Disclosure of the ZHP Parties' API processes and testing methods and process optimization strategies could cause significant commercial harm by allowing the ZHP Parties' direct competitors to benefit from the ZHP Parties' internal research and development during the pendency of the FDA's current import ban related to the Chuannan facility. Disclosing these changes to the ZHP Parties' direct competitors would put ZHP at a significant competitive disadvantage

5. **ZHP02710344** (ECF No. 1405, Ex. 15) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): This document contains internal, non-public pilot test results from May 2, 2017 to August 10, 2017 that detail the ZHP Parties' proprietary specifications and testing methods for impurities in irbesartan. These testing practices and procedures are proprietary, and unrelated to the claims at issue in this litigation. Disclosure of the ZHP Parties' testing practices and procedures to the ZHP Parties' direct competitors would result

in significant competitive harm by allowing them to benefit from the ZHP Parties' research and development while the FDA restricts the ZHP Parties from exporting its products into the U.S. market. Such disclosure would impede the ability of the ZHP Parties to compete in the highly competitive generic pharmaceutical manufacturing market.

6. **ZHP02710242** (ECF No. 1405, Ex. 16) (designated "RESTRICTED CONFIDENTIAL INFORMATION"): This document contains internal, non-public experiment results regarding the testing and validation of irbesartan samples from August 21, 2017 to December 29, 2017 that detail the ZHP Parties' proprietary specifications and testing methods for impurities in irbesartan. These testing practices and procedures are proprietary, and unrelated to the claims at issue in this litigation. Disclosure of the ZHP Parties' testing practices and procedures to the ZHP Parties' direct competitors would result in significant competitive harm by allowing them to benefit from the ZHP Parties' research and development while the FDA restricts the ZHP Parties from exporting its products into the U.S. market. Such disclosure would impede the ability of the ZHP Parties to compete in the highly competitive generic pharmaceutical manufacturing market.

I DECLARE UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES THAT TO THE BEST OF MY KNOWLEDGE THE FOREGOING IS TRUE AND CORRECT.

Executed on October 12, 2021 in Linhai (city), China (state).



, Declarant